K062658

PRIMUS® Diagnostics
A Trinity Biotech Company

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFG 807.92.

Assigned 510(k) Number: K062658

Submitter:
Primus Corporation
dba Primus Diagnostics
4231 E. 75th Terrace
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NOV 2 6 2007

Contact Person:
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Date of Summary Preparation: October 24, 2007

Device Name: TRI♦*stat*™ Instrument and A_{1Care} Assay

Device Type:
Common Name: Glycated Hemoglobin Assay
Trade Name: TRI♦*stat*™ Instrument and A_{1Care} Assay
Classification: Assay, Glycosylated Hemoglobin

Predicate Device: K891235, Primus Boronate Affinity HPLC Method

Statement of Intended Use: The Primus A1care Assay A1c test, for use with the TRI♦*stat*™ Instrument, is a rapid *in vitro* diagnostic test for measurement of the percent of glycated hemoglobin (%HbA1c) level in human blood from finger stick or venous samples for clinical laboratory and point-of-care use. Measurement of percent HbA1c is used to monitor long-term glucose control in individuals with diabetes mellitus.

Device Description:

The TRI♦*stat*™ Instrument
The Primus TRI♦*stat*™ Instrument is a small (10"Wx11"Lx4"H), *in vitro* diagnostic instrument used with the Primus A1care Assay test to quantitate HbA1c using a patented two-phase optical method. The TRI♦*stat*™ is capable of analyzing a total of 3 samples simultaneously.

Theory of measurement
The chemistry of Primus A1care Assay and that of the predicate device are comparable. However, the A1care Assay utilizes a solid phase media like that used in conventional chromatography but in a different manner. The basis of Primus' column chromatography is a boronate affinity gel that retains glycated proteins and elutes these in a secondary buffer.

The Primus A1care Assay uses the boronate affinity in a patented two-phase optical assay. The sample is mixed in an optical cuvette with a suspension of the solid phase particles in a fluorescent buffer. The buffer also contains a lysing agent to break up the red blood cells. After the glycated hemoglobin (HbA1c) adheres to the solid phase, gel particles with A1c attached separate by sedimentation. Optical measurement of hemoglobin is by fluorescence quenching. The wavelength of light absorbance by hemoglobin overlaps the wavelength of excitation of the fluorescent dye. In the presence of hemoglobin there is less light available to excite fluorescence (the quenching effect), and this effect is linear with hemoglobin concentration. The patented two-phase assay optically examines the position where the solid phase particles settle. The measurement is made before settling for total hemoglobin, and after complete settling for Hemoglobin A1c only. The HbA1c-gel sedimentation process is monitored by an optical system examining fluorescence intensities generated between the suspension and the settled solid phase, the proportion of which is factory calibrated to give results comparable to known standards.

Comparison of TRI♦*stat*™ to the Predicate Device
The candidate device and the predicate device are substantially equivalent as they employ the same affinity methodology to binding glycated hemoglobin to immobilized aminophenylboronic acid, thus providing the means of separating glycated hemoglobin from the non-glycated hemoglobins. They have the same intended use, the same indications for use, the same manufacturer, the same analyte and the same controls.

Both Primus HPLC and A1care Assay depend on separating the glycated Hb from non-glycated Hb, measuring each separately and calculating a percent of the glycated Hb. A solid phase is most often used for such separation. There are in general two types of solid phases in use. One depends on general ion exchange differences between the glycated and non-glycated species. The other method uses specific affinity for separating the glycated from the non-glycated molecules. Affinity separation is performed with a boronic acid compound known to have general affinity for sugars. The usual means for using either method, column chromatography, is replaced by the two-phase assay in the A1care Assay.

Differences between the predicate device and Primus A1care Assay are as follows. Primus HPLC methods use conventional HPLC column chromatography with a boronate affinity matrix suitable for HPLC. TRI♦*stat*™ uses the same boronate affinity principle with a boronate modified agarose matrix with suitable transparency for optical reading. TRI♦*stat*™ uses a bulk extraction of A1c into the boronate matrix that is measured in the same container as the extraction. In place of having two solution phases read sequentially as effluents from a column, as in the predicate device, TRI♦*stat*™ measures two optical phases, a total hemoglobin, suspension phase, and a settled matrix phase containing only glycated hemoglobin. Primus HPLC uses an ammonium acetate buffer at pH 9 as the solution for binding A1c to the boronate matrix. TRI♦*stat*™ uses a glycine buffer at pH 9.1 to bind A1c to its boronate matrix. In Primus HPLC there is a second buffer to

remove the A1c from the chromatography matrix and to prepare the column for the next sample. In TRI♦*stat*™ there is no removal of A1c since the measurement is made in the matrix. TRI♦*stat*™ uses a single use disposable container. The matrix is not re-used.

Feature	Predicate	TRI♦*stat*™
Chemistry	Boronate Separation	Boronate Separation
pH of Chemistry	9.0	9.1
Separation	Chromatography	Bulk
Solution Phases	2	1
Optical Phases	1	2
Matrix Use	Replenished, Re-Used	Single Use Disposable
Instrumentation	Completely Automated	Partially Automated Requires Sample Insertion and Tube Insertion in Instrument
Sample	Venous EDTA or Finger Stick	Venous EDTA or Finger Stick
Sample	Whole Blood or Pre-diluted	Applied Direct, No Dilution
Results	Results as Hemoglobin A1c, Glycated Hemoglobin, and IFCC by using standard formulas	Results as Hemoglobin A1c, Glycated Hemoglobin, and IFCC by using standard formulas
Results	Display and Print	Display Automatic, Print Optional
Printout	Automatic	Requested by Operator
Output	1 Result per 2 Minutes	3 Results per 10 Minutes
Operation	Continuous	Operator Initiated
Sample ID	Operator Input	Bar Code Reader
Calibration	With Each Run	Factory Calibrated Kit

Comparison of Indication For Use Statement from Predicate Device

The indication statement of the Primus A1care Assay and the predicate device are equivalent and contain no intended differences critical to the intended diagnostic use, safety, or effectiveness of the device when used as labeled.

Conclusion: The Primus TRI♦*stat*™ Instrument and A_{1Care} Assay A1c Test was evaluated for non-clinical and clinical performance characteristics in comprehensive studies. These studies demonstrate that the instrument and test substantially equivalent to the predicate device and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 6 2007

Primus Corporation
c/o Mr. Britt Einspahr
Manager, Quality Assurance and Compliance
4231 E. 75th Terrace
Kansas City, MO 64132

Re: k062658
Trade/Device Name: Primus A1care Assay & Primus TRI·stat™ Instrument
Regulation Number: 21 CFR §864.7470
Regulation Name: Glycosylated Hemoglobin Assay.
Regulatory Class: Class II
Product Code: LCP, JJE
Dated: October 26, 2007
Received: October 29, 2007

Dear Mr. Einspahr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062658

Device Name: Primus A1care Assay and TRI♦stat™ Instrument

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K062658